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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,816	12/12/2001	Nicholas D. Donato	270/138	8918

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 10/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,816

Applicant(s)

Donato

Examiner

Christopher Tate

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1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 14, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed July 14, 2003 is acknowledged and has been entered. Claims 1-58 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-58 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered exceedingly vague and indefinite for the following reasons:

- The process recited in claim 1 is very unclear because it is missing one or more essential steps therefrom (see, e.g., MPEP 2172.01) and, thus, is also incomplete. For example, it is completely unclear by the first step as to how the plant material is prepared (this amended phrase is totally vague and unclear with respect to adequately defining this essential step of the disclosed invention). In the second step, the essential solvent(s) by which the sample is dissolved should be particularly defined as this is clearly essential with respect to extracting the active anti-cancer agents from the plant sample. In the fourth step, it is completely unclear as to what the phrase

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"purifying said pulp fraction to product an extract ..." is defining - e.g., is this attempting to define purifying a compound from the pulp fraction, removing debris from the pulp fraction, or something else (i.e., in what manner is the pulp fraction actually purified)? Further, it is unclear as to what actually constitutes the "extract" - e.g., is it some purified compound, or product obtained from the fourth step, is it what has been removed from the purified pulp fraction, or something else (thus, the recited fourth step is totally vague and unclear with respect to adequately defining this essential step of the disclosed invention)? Since the process steps in preparing the "crude extract" as described in Example 1 of the instant specification (pages 10-11) are clearly essential in providing an extract having the anti-cancer functional effects instantly claimed, they must be adequately and fully defined in the claim language itself. It is, therefore, strongly suggested that claim 1 be fully expanded upon so as to recite all the essential steps necessary in preparing the instantly disclosed crude extract (using Example 1 as a guide) so as to clearly define a complete overall process for preparing the instantly disclosed/demonstrated plant extract to overcome this rejection.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

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Applicants' arguments concerning the above U.S.C. 112 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that they have more particularly claimed the present invention. However, amended claim 1 is actually less particularly defined than previously, including the omnibus-type first step phrase "preparing a sample of said plant" (this phrase does not in any way adequately define the essential first step of the disclosed process which involves removing the latex therefrom). Applicant further argues that, based upon the teachings of the instant specification, other essential step/element limitations within the claimed preparatory process of isolating an extract for *Euphorbia obesa* having the instantly claimed anti-cancer activities would have been recognized by one of ordinary skill in the art. However, please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654